construction contained in RUS Bulletin 1753F–150 (RUS Form 515a).

The current outside plant specifications are used by borrowers to secure the services of a contractor for the construction of telecommunications facilities. Current specifications have become outdated due to the advancements in Fiber-to-the-Home construction as well as installation methods and materials. In order for borrowers and contractors to take advantage of these improved construction installation methods and materials, the current specifications have been revised.

On Tuesday, June 8, 2010, RUS published a proposed rule in the **Federal Register** (Vol. 75, No 109, page 32313), proposing to amend its regulations on Telecommunications Policies on Specifications, Acceptable Materials, and Standard Contract Forms, by revising RUS Bulletin 1753F–150, Specifications and Drawings for Construction of Direct Buried Plant (Form 515a). Interested parties were invited to submit comments on or before August 9, 2010. No comments were received.

List of Subjects in 7 CFR Part 1755

Incorporation by reference, Loan programs—communications, Reporting and recordkeeping requirements, Rural areas, Telephone.

■ For reasons set out in the preamble, RUS proposes to amend chapter XVII of title 7 of the Code of Federal Regulations as follows:

PART 1755—TELECOMMUNICATIONS POLICIES ON SPECIFICATIONS, ACCEPTABLE MATERIALS, AND STANDARD CONTRACT FORMS

■ 1. The authority citation for part 1755 continues to read as follow:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

■ 2. In § 1755.97, the table is amended by revising the issue date of RUS Bulletin 1753F–150 to read as follows:

§ 1755.97 Incorporation by reference of telecommunications standards and specifications.

* * * * *

RUS Bulletin No.	Specification No.	Date last issued	Title of standard or specification
*	*	*	*
1753F–150	Form 515a	September 2010	Specifications and Drawings for Construction of Direct Buried Plant.
*	*	*	*

* * *

Dated: September 23, 2010.

Jonathan Adelstein,

Administrator, Rural Utilities Service.

[FR Doc. 2010–24420 Filed 9–28–10; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–0911; Airspace Docket No. 10–ASO–32]

Amendment to Class E Airspace; Smithfield, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: This action amends Class E airspace at Johnston County Airport, Smithfield, NC, by correcting an omission of the geographic coordinates of the Area Navigation (RNAV) Global Positioning System (GPS) Special Standard Instrument Approach Procedure (SIAP) serving the Johnston Memorial Hospital to aid in the navigation of our National Airspace System.

DATES: Effective 0901 UTC, January 13, 2011. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5610.

SUPPLEMENTARY INFORMATION:

History

The FAA received a request from the National Aeronautical Navigation Services to correct the omission of the geographic coordinates for the point in space serving Johnston Memorial Hospital in the amendment of the Class E airspace published in the **Federal Register** on July 27, 2010 (75 FR 43817). This action makes the adjustment.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E airspace at Smithfield, NC, by making the addition of the geographic coordinates of the RNAV (GPS) approach point in space serving Johnston Memorial Hospital to coincide with the FAAs National Aeronautical Navigation Services depiction. Accordingly, since this is an administrative change, and does not involve a change in the dimensions or operating requirements of that airspace, notice and public procedures under 5 U.S.C. 553 (b) are unnecessary.

The Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The FAA has determined that his regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator.

Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A. Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Smithfield, NC.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E Airspace Extending Upward From 700 feet or More Above the Surface of the Earth

* * * * *

ASO NC E5 Smithfield, NC [Amended]

Johnston County Airport, NC
(Lat. 35°32′27″ N., long 78°23′25″ W.)
Johnston Memorial Hospital
Point In Space Coordinates
(Lat. 35°31′23″ N., long 78°20′35″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Johnston County Airport and within 2 miles each side of the 023° bearing from the airport extending from the 6.5-mile radius to 10.2 miles northeast of the Johnston County Airport and within a 6-mile radius of the point in space (lat.35°31′23″ N., long. 78°20′35″ W.) serving Johnston Memorial Hospital.

Issued in College Park, Georgia, on September 17, 2010.

Myron A. Jenkins,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2010–24113 Filed 9–28–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 320

[Docket No. FDA–2000–N–0108] (formerly Docket No. 00N–1484)

RIN 0910–AG13

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing safety reporting requirements for human drug and biological products subject to an investigational new drug application (IND). The final rule codifies the agency's expectations for timely review, evaluation, and submission of relevant and useful safety information and implements internationally harmonized definitions and reporting standards. The revisions will improve the utility of IND safety reports, reduce the number of reports that do not contribute in a meaningful way to the developing safety profile of the drug, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, subject bioavailability and bioequivalence studies to safety reporting requirements, promote a consistent approach to safety reporting internationally, and enable the agency to better protect and promote public health.

DATES: This rule is effective March 28, 2011.

FOR FURTHER INFORMATION CONTACT:

For information on IND safety reporting for human drug products: Janet Norden, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6324, Silver Spring, MD 20993–0002, 301–796–2500.

For information on IND safety reporting for human biological products: Laura Rich, Center for Biologics Evaluation and Research, Food and Drug Administration,1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

In the **Federal Register** of March 14, 2003 (68 FR 12406), FDA issued a proposed rule to revise its regulations governing pre- and postmarketing safety